# Comparative Effect of Orthosis Design on Functional Performance

Jeanne C. Patzkowski, MD, Ryan V. Blanck, LCPO, Johnny G. Owens, MPT, Jason M. Wilken, PhD, MPT, Kevin L. Kirk, DO, Joseph C. Wenke, PhD, Joseph R. Hsu, MD, and the Skeletal Trauma Research Consortium (STReC)

*Investigation performed at San Antonio Military Medical Center, Center for the Intrepid, and the United States Army Institute of Surgical Research, Fort Sam Houston, Texas*

**Background:** High-energy extremity trauma is common in combat. Orthotic options for patients whose lower extremities have been salvaged are limited. A custom energy-storing ankle-foot orthosis, the Intrepid Dynamic Exoskeletal Orthosis (IDEO), was created and used with high-intensity rehabilitation as part of the Return to Run clinical pathway. We hypothesized that the IDEO would improve functional performance compared with a non-custom carbon fiber orthosis (BlueRocker), a posterior leaf spring orthosis, and no brace.

**Methods:** Eighteen subjects with unilateral dorsiflexion and/or plantar flexion weakness were evaluated with six functional tests while they were wearing the IDEO, BlueRocker, posterior leaf spring, or no brace. The brace order was randomized, and five trials were completed for each of the functional measures, which included a four-square step test, a sit-to-stand five times test, tests of self-selected walking velocity over level and rocky terrain, and a timed stair ascent. They also completed one trial of a forty-yard (37-m) dash, filled out a satisfaction questionnaire, and indicated whether they had ever considered an amputation and, if so, whether they still intended to proceed with it.

**Results:** Performance was significantly better with the IDEO with respect to all functional measures compared with all other bracing conditions ($p < 0.004$), with the exception of the sit-to-stand five times test, in which there was a significant improvement only as compared with the BlueRocker ($p = 0.014$). The forty-yard dash improved by approximately 35% over the values for the posterior leaf spring and no-brace conditions, and by 28% over the BlueRocker. The BlueRocker demonstrated a significant improvement in the forty-yard dash compared with no brace ($p = 0.033$), and a significant improvement in self-selected walking velocity on level terrain compared with no brace and the posterior leaf spring orthosis ($p < 0.028$). However, no significant difference was found among the posterior leaf spring, BlueRocker, and no-brace conditions with respect to any other functional measure. Thirteen patients initially considered amputation, but after completion of the clinical pathway, eight desired limb salvage, two were undecided, and three still desired amputation.

**Conclusions:** Use of the IDEO significantly improves performance on validated tests of agility, power, and speed. The majority of subjects initially considering amputation favored limb salvage after this noninvasive intervention.

**Level of Evidence:** Therapeutic Level II. See Instructions for Authors for a complete description of levels of evidence.

Extremity injuries are the most frequent combat wounds sustained by military service members in Operations Enduring Freedom and Iraqi Freedom[1]. Of these injuries, 26% are fractures, half of which affect the lower extremity; 82% of the fractures are open high-energy injuries. Treatment is complicated by soft-tissue injury, contamination,

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and neurovascular injuries[1,2]. Surgical advances have allowed surgeons to pursue limb salvage in the face of severe injuries[3-5]. Prosthetic advances have facilitated high-level function following amputation[6], but similar advances in orthotics after limb salvage have been uncommon. Many of our patients with limb salvage have been unable to achieve their desired functional goals because of volumetric muscle loss[7] as well as chronic pain and nerve injury[3,8]. Stinner et al. reported a delayed-amputation rate of 15.2% in the current military conflicts[9]. We have received requests from our patients for late amputation to improve function and decrease pain.

We previously described a novel Return to Run clinical pathway for the treatment of military personnel who have undergone limb salvage[10]. The pathway involves a multidisciplinary approach to patient care incorporating orthopaedic surgery, physical therapy, prosthetics and orthotics, physical medicine and rehabilitation, mental health, and pain management specialists. Patients are offered the utilization of a custom energy-storing ankle-foot orthosis, the Intrepid Dynamic Exoskeletal Orthosis (IDEO), in combination with a high-intensity rehabilitation program[10-12]. The purpose of this study was to compare the effect on functional performance of the IDEO against two commercially available orthoses, and no orthosis, when worn by patients with severe lower-extremity weakness. We hypothesized that use of the IDEO would improve functional performance. We further sought to determine if the IDEO would be well tolerated and would serve as an alternative to late amputation.

## Materials and Methods

Institutional review board approval was obtained prior to initiation of this prospective randomized trial. Subjects were identified from the Orthopaedic, Physical Therapy, and Prosthetics and Orthotics Clinics. Patients were considered for enrollment if they were at least eighteen years old and had unilateral lower-extremity dorsiflexion and/or plantar flexion weakness (≤4/5 muscle strength) according to the Medical Research Council scale for manual motor testing[13]. Subjects were further required to have a functional IDEO and to have completed the rehabilitation portion of the clinical pathway. Patients were excluded if they had bilateral lower-extremity injury, were unable to walk, or their weakness resulted from spinal cord or central nervous system injury. In order to include patients with complex regional pain syndrome, the presence of sensory impairment or medical comorbidities were not considered exclusion criteria unless they precluded safe testing of the functional measures. Written informed consent was obtained from all participants.

### *Intrepid Dynamic Exoskeletal Orthosis*

The IDEO is a custom orthosis created primarily from carbon fiber (Fig. 1). It incorporates a posteriorly mounted carbon fiber strut (Fig. 2) with a proximal ground-reaction cuff (Fig. 3) and a distal supramalleolar ankle-foot orthosis. The proximal ground-reaction cuff is a circumferential support fashioned in the style of a patellar-tendon-bearing prosthesis located at the proximal part of the leg, with a posterior attachment to the proximal end of the carbon fiber strut. The distal supramalleolar ankle-foot orthosis is the low-profile section spanning the ankle joint to the foot-plate complex that provides a posterior attachment to the distal end of the carbon fiber strut. The strut allows deformation of the orthosis, and the posterior position appears to increase strut dynamics and power. A cushioned heel allows shock absorption during the loading response. The foot plate, inspired by prosthetic running feet, is made of laminated carbon fiber with a gradual roller shape. The plantar flexed position of the foot plate allows increased deflection and energy storage as the tibia progresses forward from mid to terminal stance. This also allows forefoot loading during agility and running activities. The modular design allows alignment adjustment as well as the ability to change strut stiffness on the basis of individual patient strength gains, and facilitates donning and doffing to accommodate volumetric muscle changes due to strength gains or edema.

Fig. 1
Intrepid Dynamic Exoskeletal Orthosis (IDEO).

### *Physical Therapy Component of the Return to Run Clinical Pathway*

Prior to enrolling in the study, all subjects completed the physical therapy component of the clinical pathway. This is a sports-medicine-based approach that focuses on strength, agility, and speed. Patients begin the program early in their recovery, many with a circular external fixator. The program is organized into progressions, beginning with aggressive mobilization to restore as much motion at the ankle and knee as possible. Although no specific ankle joint position or motion arc is required to utilize the IDEO or participate in the rehabilitation program, knee flexion of <90° appears to substantially hinder patient performance with the IDEO. The strength component of the program is comprehensive. Exercises are designed to build strength in the core musculature in the upper and lower body. These include upper-body

Fig. 2
Posterior carbon fiber strut of the IDEO.

pulling (rowing, chin-ups) and pushing (push-ups, bench presses) as well as lower-body pulling (dead lifts, bridge) and pushing (squats, leg presses). Total-body plyometrics and power movements are utilized. Strengthening progresses from bilateral stance to lunging or split squat patterns. Eccentric exercises allow for quick deceleration, which is essential for most recreational sports activities. Initial agility exercises are performed in a linear fashion and progress to multiple directions. Plyometric work begins early, typically starting with horizontal plane exercises and progressing to vertical (upright) exercises in the IDEO phase. The progression to running requires the patient to adopt a midfoot strike, as the combination of a heel strike with the plantar flexed foot plate leads to knee hyperextension. On average, patients require up to twelve weeks to complete the IDEO and running phase of the program.

### *Functional Measure Testing*

Subjects were tested under four bracing conditions: wearing the IDEO, the BlueRocker (Allard International, Helsingborg, Sweden), a rigid plastic posterior leaf spring, and their own athletic shoes with no brace. The BlueRocker is a commercial prefabricated orthosis consisting of a pretibial shell that merges into a carbon fiber spring that descends along the lateral aspect of the ankle and connects distally with a carbon fiber foot plate. It is indicated for use in treating foot drop, severe ankle instability, and weakness in multiple leg muscle groups[14]. The posterior leaf spring used in this study is a generic, commercially available prefabricated orthosis created from rigid plastic, and it is indicated for treatment of foot drop. The BlueRocker and posterior leaf spring were chosen as they have historically been used at our institution for patients with ankle weakness and are still used when patients are being considered for IDEO fitting.

The order of brace wear was randomized for testing. All testing was performed in one session, and all four bracing conditions were tested for one measure before moving to the next. If a subject reported pain or skin irritation in a particular brace, its use was discontinued for the remainder of the testing. Subjects were not tested with the posterior leaf spring on if they had no demonstrable foot drop (≤3/5 muscle strength) or if they had a rigid equinus deformity, ankle fusion, or any condition preventing comfortable placement of the orthosis.

Five functional measures, listed below, have been used as validated measures of functional assessment[15-20]. These measures have been validated for a young active-duty population at our institution[21], and data collected from these healthy, uninjured subjects were used as normative values for comparison. Five trials of each functional measure were completed under each bracing condition, with the exception of the forty-yard (37-m) dash, in which one trial was performed with two independent observers using hand timers.

The four-square step test is a dynamic test of balance and agility[16]. Subjects were instructed to stand in the bottom left corner of a Maltese cross shape delineated by a one-inch (2.5-cm) obstacle lying flat on the ground (Fig. 4). They were instructed to move both feet into each square (one foot at a time, maintaining one foot in contact with the ground) in the following order: (1) forward, (2) sidestep to the right, (3) backward, and (4) sideways to the left as fast as possible. This was repeated in the opposite direction, and the time needed to return to the original square was recorded. Five trials were completed, and the average time needed to complete the measure was calculated.

The sit-to-stand five times test is commonly performed to assess lower-extremity strength, endurance, and mobility[20]. Subjects were instructed to sit in a standard office chair with their knees flexed 90° and their back in contact with the chair. They were asked to stand up and sit down five times, with their arms crossed, bringing their knees to full extension. The timer was stopped once their back was once again resting against the chair. Five trials were completed, and the average time needed to complete the measure was calculated.

Fig. 3
Proximal ground-reaction cuff of the IDEO.

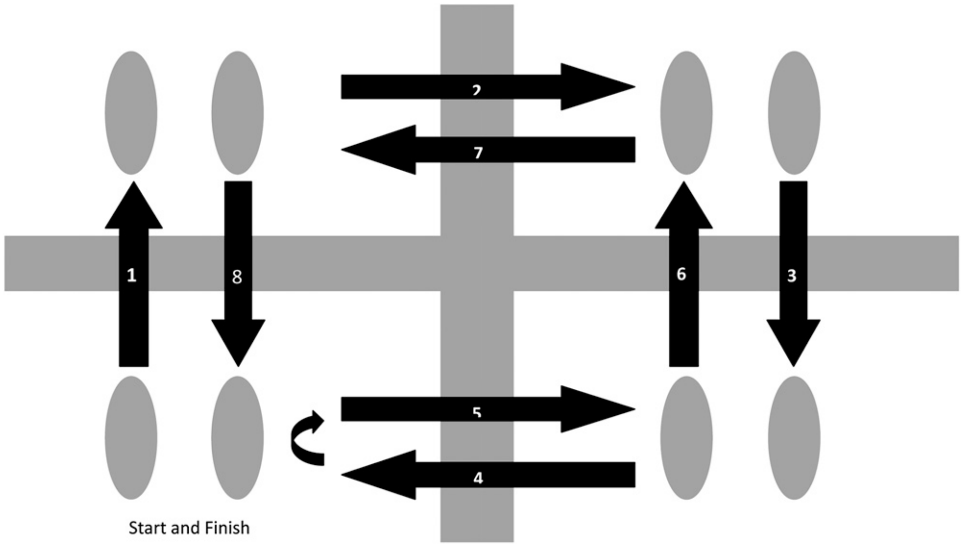


Fig. 4
Schematic representation of the four-square step test.

Timed stair ascent is often used as an objective measure of mobility and power[18]. The test was performed on a standard twelve-step staircase. Patients were instructed to ascend the staircase as fast as safely possible without using the hand railing and making contact with each step. The time needed to place both feet on the top step was recorded. Five trials were completed, and the average time needed to complete the measure was calculated.

Self-selected walking velocity over level terrain is a commonly used measure of general physical capacity. A decrement in gait speed has been identified as an early indicator of reduced participation in activities, and walking is often the first activity in which adults become dependent on assistive devices[14]. Subjects were instructed to walk at a comfortable pace down an empty hallway with smooth flooring. The time required to travel 15 m was recorded, and the average velocity of the five trials was calculated. Self-selected walking velocity over rocky terrain is a measure of speed that incorporates an uneven surface. Uneven or compliant terrain has been shown to influence gait parameters[19]. Subjects were instructed to walk at a comfortable pace between two markers separated by 6 m over a rock pit. The time needed to traverse the 6 m was recorded, and the average velocity of the five trials was calculated.

In addition to the measures listed above, each patient completed a forty-yard dash. The test was performed on a straight level path. The timer was started once the patient began to move and was stopped once he crossed the finish line. The average value of the two timers was calculated.

### *Satisfaction Questionnaire*

At the conclusion of testing, each patient filled out a satisfaction questionnaire (see Appendix). This survey was created at our institution for the purpose of this research. The first section addresses comfort, ease of use, and durability of the IDEO. The middle section asks patients to compare the various orthoses in terms of time to discomfort, daily use, cosmetic appearance, and overall preference. Lastly, patients are asked if they ever considered amputation of the injured limb; if so, why; if they now favor limb salvage; and if no, why.

### *Statistical Methods*

The study was powered to detect a difference of one standard deviation between bracing conditions, with a beta of 0.8. A repeated-measures analysis of variance (ANOVA) with a Bonferroni correction was used to detect the overall significance of the difference between conditions within each functional measure. Paired t tests were then used to determine significance between each pair of bracing conditions for each functional measure. Significance was set at $p < 0.05$ for the entire experiment; therefore, significance for each of the ANOVAs (for six different functional measures) was set at $p < 0.00833$.

### *Source of Funding*

There was no source of external funding for this study.

## Results

Eighteen male active-duty subjects between the ages of eighteen and forty-nine years (average, thirty-one years; standard deviation, 7.8) were enrolled. The average body mass index was 28.5 kg/m$^2$ (standard deviation, 3.4). Sixteen patients had a high-energy injury. Mechanisms of injury, injury characteristics, and patterns of motor weakness are shown in Table I. Of the fourteen subjects with ankle dorsiflexion weakness, eleven had weakness resulting in foot drop (≤3/5 muscle strength) and underwent testing while wearing the posterior leaf spring. Sixteen subjects completed all testing while wearing the BlueRocker; two were unable to do so secondary to lateral ankle discomfort. All subjects had completed the physical therapy component of the Return to Run clinical pathway, as determined by their primary therapist.

### *Functional Measures*

Performance was significantly better with use of the IDEO compared with all other bracing conditions for all functional measures (Table II, Fig. 5), with the exception of the sit-to-stand five times test. In that test, there was a significant improvement (of 0.9 second [s]; 10%) only when the IDEO was compared with the BlueRocker. In the four-square step test, there was a 1.2-s improvement (17%) compared with no brace and the BlueRocker, and a 0.7-s improvement (11%) over the posterior leaf spring. In the timed stair ascent, there was a 1.1-s improvement (16%) over no brace, a 1.4-s

**TABLE I Mechanism of Injury, Injury Characteristics, and Pattern of Weakness**

| | Total |
|---|---|
| Mechanism of injury | |
| Explosion | 6 |
| Gunshot wound | 4 |
| Motor-vehicle collision | 4 |
| Fall from height | 2 |
| Iatrogenic | 1 |
| Sports injury | 1 |
| Injury characteristics | |
| Peroneal nerve palsy | 5 |
| Tibial fracture (closed) | 4 |
| Tibial fracture (open) | 2 |
| Ankle fracture (including pilon and talus) | 4 |
| Multiple metatarsal fractures | 2 |
| Calcaneal fracture | 2 |
| Knee dislocation | 1 |
| Tibial nerve palsy | 1 |
| Femoral fracture | 1 |
| Achilles tendon deficiency | 1 |
| Compartment syndrome (anterior and lateral) | 1 |
| Pattern of weakness (≤4/5 muscle strength) | |
| Plantar flexion | 4 |
| Dorsiflexion | 2 |
| Mixed | 12 |

improvement (20%) over the posterior leaf spring, and a 1.7-s improvement (23%) over the BlueRocker. The IDEO allowed improvements of 0.19 meter/second (m/s) (15%) over the BlueRocker, 0.22 m/s (17%) over the posterior leaf spring, and 0.25 m/s (20%) over no brace in self-selected walking velocity on level terrain and 0.2 m/s (18%) over all three in self-selected walking velocity on rocky terrain. The largest improvements were seen in the forty-yard dash, with a 4.9-s improvement (37%) over no brace, 4.3-s improvement (34%) over the posterior leaf spring, and a 3.4-s improvement (28%) over the BlueRocker.

Performance with use of the BlueRocker was significantly faster (by 1.5 s; 11%) over that with no brace in the forty-yard dash, but there was no significant difference between the BlueRocker and the posterior leaf spring in that test. In the test of self-selected walking velocity on level terrain, performance with use of the BlueRocker was significant improved over that with the posterior leaf spring (by 0.03 m/s; 2%) and that with no brace (by 0.06 m/s; 5%). There was no significant difference among the BlueRocker, posterior leaf spring, and no brace with regard to any other functional measure.

### *Satisfaction Questionnaire*

Results of the survey demonstrated that the IDEO was very comfortable (8.3/10) and was associated with minimal skin discomfort (7.5/10), easy to put on and take off (8/10), easy to keep clean (9.5/10), and very durable (9.2/10). The median time to discomfort was thirty minutes in the posterior leaf spring, forty minutes in the BlueRocker, and ten hours in the IDEO. When all factors (cosmetic appearance, function, and comfort) were considered, the IDEO was preferred by seventeen patients while one subject preferred the posterior leaf spring. When only cosmetic appearance was considered, the IDEO was considered the more attractive option by fourteen subjects, whereas three subjects preferred the posterior leaf spring and one preferred the BlueRocker.

Thirteen of the eighteen patients reported that they had initially considered amputation of the injured leg. All thirteen reported pain, eleven cited weakness, and eleven cited activity limitations as major factors influencing their thinking. After completion of the clinical pathway, eight of the thirteen favored limb salvage, two were undecided, and three wanted to proceed with amputation. Of those who wanted to proceed with amputation, all reported pain and two reported activity limitations as the major factors influencing their decision.

**TABLE II Results of Functional Measure Testing***

| | No Brace (N = 18) | Posterior Leaf Spring (N = 11) | BlueRocker (N = 16) | IDEO (N = 18) |
|---|---|---|---|---|
| Four-square step test *(s)* | 7.0 ± 2.0$^{a}$ (3.1-12.4) | 6.5 ± 2.1$^{a}$ (3.9-10.5) | 6.9 ± 1.9$^{a}$ (4.2-11.3) | 5.8 ± 1.8$^{b}$ (3.1-10.0) |
| Sit-to-stand 5 times *(s)* | 8.5 ± 2.0$^{a,b}$ (4.8-12.6) | 8.6 ± 2.0$^{a,b}$ (4.6-12.4) | 9.1 ± 1.9$^{a,c}$ (5.1-13.3) | 8.2 ± 1.8$^{b}$ (5.2-13.6) |
| Timed stair ascent *(s)* | 6.8 ± 1.6$^{a}$ (3.9-11.5) | 7.1 ± 1.7$^{a}$ (3.7-10.5) | 7.4 ± 2.6$^{a}$ (5.0-24.4) | 5.7 ± 1.3$^{b}$ (3.0-8.6) |
| Self-selected walking velocity *(m/s)* | | | | |
| On level terrain | 1.25 ± 0.23$^{a}$ (0.96-2.09) | 1.28 ± 0.24$^{a}$ (1.02-2.18) | 1.31 ± 0.14$^{b}$ (1.00-1.63) | 1.50 ± 0.32$^{c}$ (1.22-3.04) |
| On rocky terrain | 1.12 ± 0.23$^{a}$ (0.85-2.00) | 1.11 ± 0.38$^{a}$ (0.78-2.34) | 1.12 ± 0.14$^{a}$ (0.88-1.46) | 1.32 ± 0.34$^{b}$ (0.78-2.67) |
| 40-yd dash *(s)* | 13.4 ± 5.3$^{a}$ (7.0-25.9) | 12.8 ± 4.1$^{a,b}$ (7.6-21.6) | 11.9 ± 4.1$^{b}$ (6.4-21.7) | 8.5 ± 2.4$^{c}$ (5.3-14.6) |

*The values are given as means and standard deviation with the range in parentheses. An "a" indicates that the group is significantly different from the groups labeled with a "b" or "c." A "b" indicates that the group is significantly different from the groups labeled with an "a" or "c." A "c" indicates that the group is significantly different from the groups labeled with an "a" or "b." Groups that share a letter are not significantly different from one another. Different letters signify a difference among groups ($p < 0.05$).

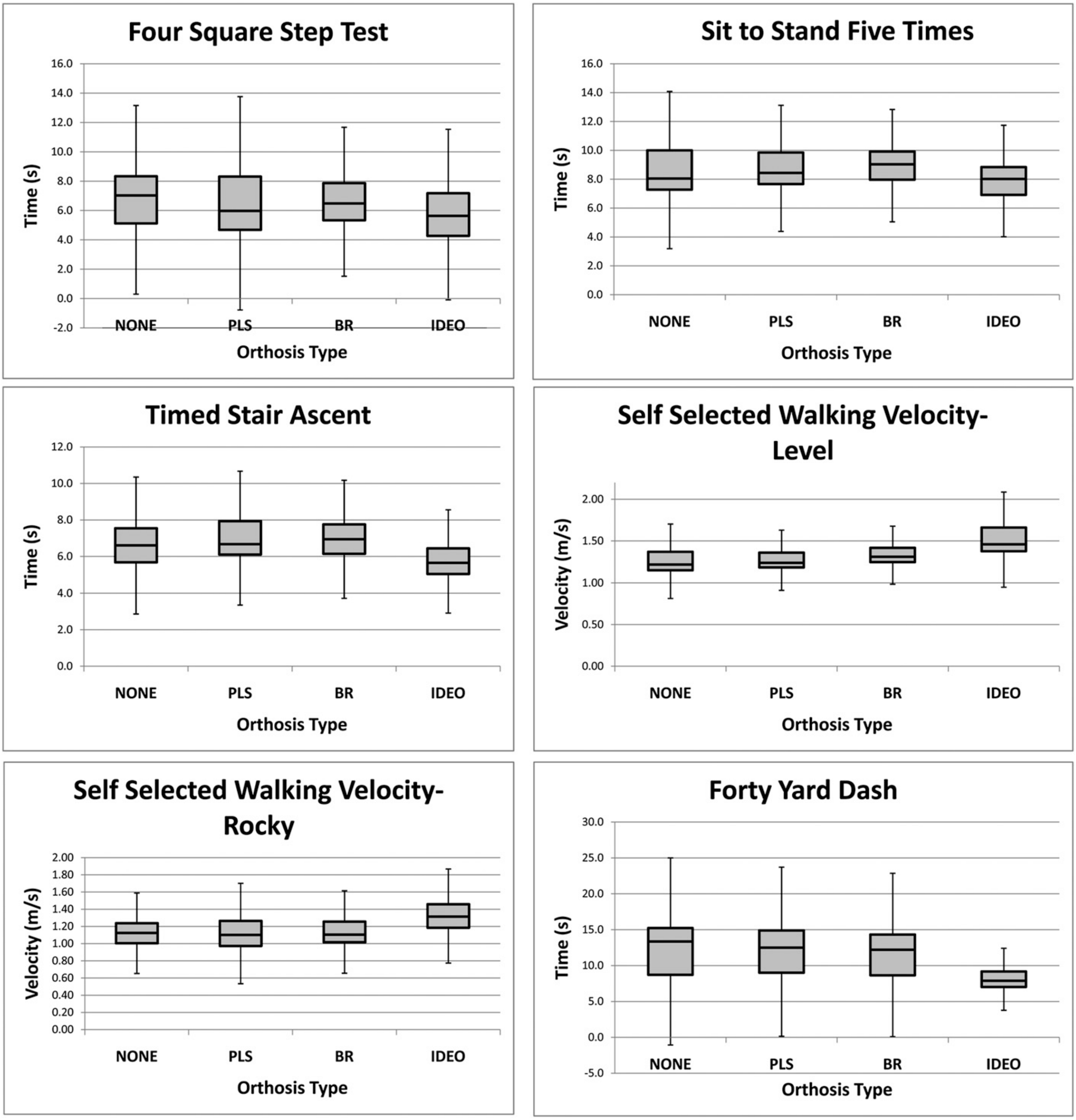


Fig. 5

Graphical representation of the results of the functional measure testing. NONE = no brace, PLS = posterior leaf spring, BR = BlueRocker, IDEO = Intrepid Dynamic Exoskeletal Orthosis.

## Discussion

Restoring physical function is difficult after limb salvage following high-energy lower-extremity trauma. At two and seven years after injury, the Lower Extremity Assessment Project (LEAP) study group found no difference in outcomes between patients who had undergone immediate amputation and those treated with limb salvage; both groups, however, were considered significantly disabled[22,23]. One of the factors listed as having a strong correlation with a positive outcome was self-efficacy, or confidence in being able to perform specific tasks or activities[24].

Limb salvage in military casualties presents a unique challenge. The high-energy wounding mechanisms frequently lead to severe neurovascular and soft-tissue compromise as well as gross contamination. Nerve injuries, chronic pain, and volumetric muscle loss complicate surgical management and rehabilitation[2,3,7,8]. Active-duty personnel were excluded from the LEAP study, and to our knowledge no studies have analyzed the effect of severe trauma on the self-efficacy of military personnel. In a recent qualitative analysis of patients with a severe open tibial fracture, 50% of those who expressed second thoughts regarding limb salvage or delayed amputation had been high-level athletes prior to their injury. The authors surmised that activity limitation was a major factor influencing their dissatisfaction with the limb salvage[25]. This has become evident in our population of patients treated with limb salvage after sustaining a combat wound. As they witness their amputee counterparts progressing through rehabilitation at a quicker pace, and performing more physically demanding athletic activities, many express frustration with their limitations and request delayed amputation in the hope of improving their functional performance[10-12].

Advances in prosthetic technology appear to have greatly increased the functional performance of lower-extremity amputees[3,6]. Orthotic options following limb salvage have mostly been limited to plastic posterior leaf spring orthoses. While these devices can correct foot drop in midstance, they do not provide dynamic energy return[26]. Energy-storing carbon fiber orthoses have improved abnormal gait patterns, temporospatial parameters, stride length, ankle power, and range of motion in small series of patients[27-30]. These studies have addressed children with cerebral palsy, myelomeningocele, or other motor disorders, or adults with hemiplegia. To our knowledge, no study to date has investigated the use of energy-storing orthoses in a population that underwent limb salvage following a traumatic injury. Furthermore, the effectiveness of these orthoses compared with that of other commercially available options has not been adequately studied.

To our knowledge, this is the first study to address the use of energy-storing ankle-foot orthoses in a population treated predominantly with limb salvage. A major strength of this study is the use of validated functional measures that are easy to perform and require minimal equipment. Additionally, this study compared the effectiveness of the IDEO and with that of other commercially available orthoses. The comparison orthoses were made of both carbon fiber and rigid plastic and are readily available at routine orthotic establishments. The no-brace condition was included to act as an internal control for the subjects, allowing assessment of the orthosis effect independent of the rehabilitation portion of the clinical pathway. It also allowed us to avoid confounding the results, as shoes alone may improve gait parameters compared with bare feet[31].

As of March 2011, over ninety patients have been fitted with, or are in the process of being fitted with, an IDEO. The earliest of these was in December 2008, and the majority of the patients were fitted within the two years prior to the time of writing; thus, it is difficult to draw conclusions regarding long-term results. Our findings demonstrate good short-term acceptance of the device in a small cohort. While we know that several of our patients have returned to active military duty, have been deployed to combat, and participate in recreational endurance sports[12], we cannot assume that this is the case for the majority of our population. At this point, we have not formally studied the long-term acceptance of the IDEO or the long-term effects of the Return to Run clinical pathway.

We acknowledge several limitations of this study. We assessed a small cohort consisting of a heterogeneous patient population. While we collected a large amount of data, we cannot group the patients into meaningful categories in the hope of delineating which patients would benefit the most from the clinical pathway. We have demonstrated the comparative effectiveness of the IDEO, but we have yet to determine the impact of the rehabilitation alone. The Return to Run clinical pathway is unique to our institution. Although we believe that the multidisciplinary approach is an important factor in our patients' improvements, further study is required to prove this. We utilized a nonvalidated survey as part of our methods. We are unaware of an existing validated measure that would allow us to capture subjective information about the IDEO and assess subject preferences regarding delayed amputation versus limb salvage. Additionally, the functional measures tested in our study represent a small portion of total physical activity and do not necessarily correlate with a patient's ability to perform longer-duration aerobic activity. Future studies are planned that will include a thorough biomechanical analysis of the IDEO and metabolic testing to systematically investigate these potential benefits. It should be noted that there is also an increased probability of finding statistical differences in studies that involve multiple comparisons. We adjusted the p value to reduce the chance of us incorrectly declaring significance. Lastly, our active-duty population lacks external validity when compared with a civilian population treated with limb salvage following traumatic injury.

Our results demonstrate that the functional performance of patients wearing the IDEO is significantly better, with regard to all functional measures, compared with all other bracing conditions with the sole exception of the sit-to-stand five times test. In that test, the IDEO performed better than the BlueRocker, which actually performed worse than the no-brace condition, but the IDEO did not significantly outperform the posterior leaf spring or no brace. This is not surprising given that the test relies more on power at the quadriceps and core musculature than power at the ankle. Furthermore, ankle mobility is a key requirement of the test, and the IDEO restricts motion at the ankle more than the other conditions do. Of note, use of the IDEO allowed patients to perform the four-square step test and self-selected walking velocity test on both level and rocky terrain at the same speed as was achieved by the healthy, uninjured control subjects reported on by Wilken (5.7 s, 1.50 m/s, and 1.24 m/s, respectively)[21]. We suspect that the unique design of the IDEO, which presumably allows for dynamic energy storage and return, is responsible for these results. A formal biomechanical analysis is currently under way at our institution to fully characterize the effect of the device on ankle power, motion, and work. While the BlueRocker allowed small but significant improvements in performance as compared with no brace in the forty-yard dash, and compared with no brace and the posterior leaf spring in self-selected walking velocity on level terrain, there was no significant difference among the BlueRocker, posterior leaf spring, and no brace with respect to any other functional measure.

The IDEO was reported to be very comfortable, easy to use, and durable. It was the overall preferred orthosis and was considered the cosmetically superior option. Patients were able to wear the IDEO nearly fifteen times longer than the BlueRocker and twenty times longer than the posterior leaf spring without discomfort. Prior to entrance into the Return to Run clinical pathway, thirteen of our patients stated that they were actively considering amputation of the injured limb because of pain, weakness, and activity limitations. Eight of these patients since countermanded their request and favored limb salvage at the conclusion of this noninvasive intervention. The three who still favored amputation cited pain and activity limitations as the main reasons for their decision.

In conclusion, the IDEO leads to significantly improved functional performance, is well-tolerated, and may serve as an alternative to late amputation for patients with severe weakness about the leg and ankle. Further research efforts include a formal biomechanical analysis of the IDEO, metabolic testing, and expansion of the study to civilian trauma centers to assess external validity.

## Appendix

eA The Subject Satisfaction Questionnaire is available with the online version of this article as a data supplement at jbjs.org. ■

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Jeanne C. Patzkowski, MD
Kevin L. Kirk, DO
Orthopaedic Surgery Service, Department of Orthopaedics and Rehabilitation, San Antonio Military Medical Center, 3851 Roger Brooke Drive, Fort Sam Houston, TX 78234.
E-mail address for J.C. Patzkowski: Jeanne.patzkowski2@amedd.army.mil

Ryan V. Blanck, LCPO
Johnny G. Owens, MPT
Jason M. Wilken, PhD, MPT
Prosthetics and Orthotics Department (R.V.B.), Physical Therapy Department (J.G.O.), and Military Performance Laboratory (J.M.W.), Center for the Intrepid, San Antonio Military Medical Center, 3851 Roger Brooke Drive, Fort Sam Houston, TX 78234

Joseph C. Wenke, PhD
Joseph R. Hsu, MD
Department of Extremity Trauma and Regenerative Medicine (J.C.W.) and Orthopaedic Trauma Service (J.R.H.), United States Army Institute of Surgical Research, 3698 Chambers Pass, Fort Sam Houston, TX 78234

## References

**1.** Owens BD, Kragh JF Jr, Macaitis J, Svoboda SJ, Wenke JC. Characterization of extremity wounds in Operation Iraqi Freedom and Operation Enduring Freedom. J Orthop Trauma. 2007;21:254-7.

**2.** Ursone RL. Unique complications of foot and ankle injuries secondary to warfare. Foot Ankle Clin. 2010;15:201-8.

**3.** Shawen SB, Keeling JJ, Branstetter J, Kirk KL, Ficke JR. The mangled foot and leg: salvage versus amputation. Foot Ankle Clin. 2010;15:63-75.

**4.** Beltran MJ, Ochoa LM, Graves RM, Hsu JR. Composite bone and soft tissue loss treated with distraction histiogenesis. J Surg Orthop Adv. 2010;19:23-8.

**5.** Keeling JJ, Gwinn DE, Tintle SM, Andersen RC, McGuigan FX. Short-term outcomes of severe open wartime tibial fractures treated with ring external fixation. J Bone Joint Surg Am. 2008;90:2643-51.

**6.** Fergason J, Keeling JJ, Bluman EM. Recent advances in lower extremity amputations and prosthetics for the combat injured patient. Foot Ankle Clin. 2010;15:151-74.

**7.** Grogan BF, Hsu JR. Skeletal Trauma Research Consortium. Volumetric muscle loss. J Am Acad Orthop Surg. 2011;19 Suppl 1:S35-7.

**8.** Pollak AN, Ficke JR. Extremity War Injuries III Session Moderators. Extremity war injuries: challenges in definitive reconstruction. J Am Acad Orthop Surg. 2008;16:628-34.

**9.** Stinner DJ, Burns TC, Kirk KL, Scoville CR, Ficke JR, Hsu JR. Late Amputation Study Team. Prevalence of late amputations during the current conflicts in Afghanistan and Iraq. Mil Med. 2010;175:1027-30.

**10.** Patzkowski JC, Blanck RV, Owens JG, Wilken JM, Blair JA, Hsu JR. Can an ankle-foot orthosis change hearts and minds? J Surg Orthop Adv. 2011;20:8-18.

**11.** Owens JG. Physical therapy of the patient with foot and ankle injuries sustained in combat. Foot Ankle Clin. 2010;15:175-86.

**12.** Owens JG, Blair JA, Patzkowski JC, Blanck RV, Hsu JR. Skeletal Trauma Research Consortium. Return to running and sports participation after limb salvage. J Trauma. 2011;71(1 Suppl):S120-4.

**13.** Compston A. Aids to the investigation of peripheral nerve injuries. Medical Research Council: Nerve Injuries Research Committee. Brain. 2010;133:2838-44.

**14.** BlueRocker. www.allardint.com/index.html. Accessed 2011 Dec 9.

**15.** Boonstra AM, Fidler V, Eisma WH. Walking speed of normal subjects and amputees: aspects of validity of gait analysis. Prosthet Orthot Int. 1993;17:78-82.

**16.** Dite W, Temple VA. A clinical test of stepping and change of direction to identify multiple falling older adults. Arch Phys Med Rehabil. 2002;83:1566-71.

**17.** Fried LP, Bandeen-Roche K, Chaves PH, Johnson BA. Preclinical mobility disability predicts incident mobility disability in older women. J Gerontol A Biol Sci Med Sci. 2000;55:M43-52.

**18.** Hughes C, Osman C, Woods AK. Relationship among performance on stair ambulation, functional reach, and timed up and go tests in older adults. Issues on Aging. 1998;21:18-22.

**19.** Paysant J, Beyaert C, Datié AM, Martinet N, André JM. Influence of terrain on metabolic and temporal gait characteristics of unilateral transtibial amputees. J Rehabil Res Dev. 2006;43:153-60.

**20.** Whitney SL, Wrisley DM, Marchetti GF, Gee MA, Redfern MS, Furman JM. Clinical measurement of sit-to-stand performance in people with balance disorders: validity of data for the Five-Times-Sit-to-Stand Test. Phys Ther. 2005;85:1034-45.

**21.** Wilken JM, Darter BJ, Goffar SL, Ellwein JC, Snell RM, Tomalis EA, Shaffer SW. Physical performance assessment in military service members. J Am Acad Orthop Surg. In Press.

**22.** Bosse MJ, MacKenzie EJ, Kellam JF, Burgess AR, Webb LX, Swiontkowski MF, Sanders RW, Jones AL, McAndrew MP, Patterson BM, McCarthy ML, Travison TG, Castillo RC. An analysis of outcomes of reconstruction or amputation after leg-threatening injuries. N Engl J Med. 2002;347:1924-31.

**23.** MacKenzie EJ, Bosse MJ, Pollak AN, Webb LX, Swiontkowski MF, Kellam JF, Smith DG, Sanders RW, Jones AL, Starr AJ, McAndrew MP, Patterson BM, Burgess AR, Castillo RC. Long-term persistence of disability following severe lower-limb trauma. Results of a seven-year follow-up. J Bone Joint Surg Am. 2005;87:1801-9.

**24.** MacKenzie EJ, Bosse MJ. Factors influencing outcome following limb-threatening lower limb trauma: lessons learned from the Lower Extremity Assessment Project (LEAP). J Am Acad Orthop Surg. 2006;14(10 Spec No):S205-10.

**25.** Aravind M, Shauver MJ, Chung KC. A qualitative analysis of the decision-making process for patients with severe lower leg trauma. Plast Reconstr Surg. 2010;126:2019-29.

**26.** Ounpuu S, Bell KJ, Davis RB 3rd, DeLuca PA. An evaluation of the posterior leaf spring orthosis using joint kinematics and kinetics. J Pediatr Orthop. 1996;16:378-84.

**27.** Bartonek A, Eriksson M, Gutierrez-Farewik EM. A new carbon fibre spring orthosis for children with plantarflexor weakness. Gait Posture. 2007;25:652-6.

**28.** Bartonek A, Eriksson M, Gutierrez-Farewik EM. Effects of carbon fibre spring orthoses on gait in ambulatory children with motor disorders and plantarflexor weakness. Dev Med Child Neurol. 2007;49:615-20.

**29.** Bleyenheuft C, Caty G, Lejeune T, Detrembleur C. Assessment of the Chignon dynamic ankle-foot orthosis using instrumented gait analysis in hemiparetic adults. Ann Readap Med Phys. 2008;51:154-60.

**30.** Wolf SI, Alimusaj M, Rettig O, Döderlein L. Dynamic assist by carbon fiber spring AFOs for patients with myelomeningocele. Gait Post. 2008;28:175-7.

**31.** Churchill AJ, Halligan PW, Wade DT. Relative contribution of footwear to the efficacy of ankle-foot orthoses. Clin Rehabil. 2003;17:553-7.